IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

DEY, L. P. and DEY, INC.,

Plaintiffs,

v. // CIVIL ACTION NO. 1:09CV87
(Judge Keeley)

TEVA PARENTERAL MEDICINES, INC.,
TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.

ORDER GRANTING PLAINTIFFS'
MOTION FOR PARTIAL SUMMARY JUDGMENT [DKT. NO. 159]

Pending before the Court is the Motion for Partial Summary Judgment of the plaintiffs, Dey, L.P. and Dey Inc. (collectively "Dey"). (Dkt. No. 159). Dey seeks summary judgment as to whether the proposed production and marketing of a generic version of Perforomist® by the defendants, Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries, Ltd. (collectively "Teva"), will infringe two claims of one of Dey's family of patents for that drug. For the reasons discussed below, the Court **GRANTS** Dey's motion. (Dkt. No. 159).

I. FACTS AND PROCEDURAL HISTORY

A.

This patent infringement case involves four United States Patents issued to Dey, including 6,667,344 ("the '344 Patent"), 6,814,953 ("the '953 Patent"), 7,348,362 ("the '362 Patent"), and 7,462,645 ("the '645 Patent") (collectively, the "patents-in-suit"). The '344 and '953 Patents, entitled "Bronchodilating

Compositions and Methods," derive from provisional U.S. patent application 60/284,606 and share essentially identical specifications. The '362 and '645 Patents, entitled "Bronchodilating Beta-Agonist Compositions and Methods," derive from provisional U.S. patent application 60/486,386. They too share essentially identical specifications that closely resemble those of the '344 and '953 Patents.

The patents-in-suit cover aqueous compositions of formoterol that allow the compositions to remain suitable for direct administration during long-term storage. They also cover methods for using these compositions to treat broncho-constrictive disorders. Dey uses the formulations and methods described in these patents in a commercial product known as Perforomist®.

In a letter dated May 12, 2009, Teva, the world's largest manufacturer of generic drugs, notified Dey that it had filed an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration ("FDA") approval to market a generic version of Perforomist® (Teva's "proposed generic drug product"). Teva also filed a certification with the FDA alleging that the four patents issued to Dey for Perforomist® are invalid, unenforceable, and not infringed by Teva's manufacture or sale of the proposed generic drug product. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Dey responded to Teva's ANDA by filing this lawsuit under the Hatch-Waxman Act, which "gives a drug patent owner the right to bring an action for infringement upon the filing of a paragraph IV certification." Bristol-Myers Squibb Co. v. Royce Laboratories, Inc., 69 F.3d 1130, 1135 (Fed. Cir. 1995) (citing 35 U.S.C. § 271(e)(2)(A)). Dey alleges that Teva's proposed generic drug product infringes on certain claims in the patents-in-suit, specifically claims 1-14, 16-22, 27-31, 33-39, 48, 61-62, 65, and 69-74 of the '344 Patent, claims 1-13, 15-21, 26-30, 32-38, 58-63, 74-86, 90-94, 99-103, 105-111, and 131-136 of the '953 Patent, claims 1-15 of the '362 Patent, and claims 1-3, and 5-9 of the '645 Patent (collectively, the "asserted claims").

B.

Following briefing and a hearing on the parties' proposed claim constructions, on June 17, 2011, the Court entered an Order that construed the contested claim terms as follows:

1. "**Formulated at a concentration suitable for direct administration**" means "ready to administer directly to a subject in need thereof, without mixing or diluting;"
2. "**Pharmaceutical composition**" means "a medicinal formulation containing an active drug and inert excipients;"

3. "**Shelf life**" means "the period of time during which a drug may be stored and remains suitable for use;" and
4. "**Formulated for single dosage administration**" means "formulated in a quantity that is taken or administered at one time."

(Dkt. No. 99).

The Court also adopted the parties' agreed constructions of the following terms:

1. "**Stable during long term storage**" means "the composition has an estimated shelf-life of greater than 1, 2 or 3 months usage time at 25° C and greater than or equal to 1, 2 or 3 years storage time at 5° C;"
2. "**Article of manufacture**" means something that "contains (1) packaging material, (2) a composition, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and (3) a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction;"

3. "**Packaging material or pharmaceutical packaging material**" means "blister packs, bottles, tubes, inhalers, pumps, bags, vials, containers, syringes, bottles, and any packaging material suitable for a selected formulation and intended mode of administration and treatment;"

4. "**Label**" means "Printed matter included with the article of manufacture that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction."

5. "**Nebulizer/Nebulized**" means:

> "'**Nebulizer**': instrument that is capable of generating very fine liquid droplets for inhalation into the lung. Within this instrument, the nebulizing liquid or solution is atomized into a mist of droplets with a broad size distribution by methods known to those of skill in the art, including, but not limited to, compressed air, ultrasonic waves, or a vibrating orifice;"
>
> "'**Nebulized**': a liquid or solution composition that has been atomized into a mist of droplets with a broad size distribution by an instrument that

utilizes methods known to those of skill in the art, including, but not limited to, compressed air, ultrasonic waves, or a vibrating orifice;" and

6. "**Without dilution or other modification**" means "a pharmaceutical composition that has not been diluted or changed in any other way."

Id.

C.

On September 21, 2012, Dey filed a motion for partial summary judgment. Based on this Court's claim construction, it asserted that Teva's proposed generic drug product infringes every element of claims 1 and 65 of the '344 Patent. (Dkt. No. 160 at 4). In its response to the motion, Teva contended that, because the formterol fumarate inhalation solution (the "formoterol solution") in its proposed generic drug product degrades when exposed to sunlight, if not protected by a foil overwrap, its product was not "stable during long-term storage," and consequently did not satisfy the elements of either claim 1 or claim 65, which depends upon claim 1. Teva also contended that its proposed generic drug product does not include the "label" required by claim 65.[1] Dey's reply reiterated

[1] Teva also filed a fifty-six page document entitled "Teva's Response to Plaintiffs' Apparent Statement of Facts and Teva's Rebuttal Statement of Additional Material Facts in Opposition to Dey's Motion for Partial Summary Judgment." (Dkt. No. 163-1). As noted by Dey, this

that Teva's proposed generic drug product infringes all elements of claims 1 and 65 of the '344 Patent.

II. SUMMARY JUDGMENT STANDARD

"An issue may be decided by summary judgment when no question of material fact is in dispute, or when the nonmovant cannot prevail as a matter of law, even on its view of the facts and evidence." Ateliers de la Haute-Garonne v. Broetje Automation USA Inc., No. 2012-1038, 2013 WL 2181239, at *4 (Fed. Cir. May 21, 2013) (citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251–52 (1986) (citing Fed. R. Civ. P. 56(c)); Allied Colloids, Inc. v. American Cyanamid Co., 64 F.3d 1570, 1573 (Fed. Cir. 1995)). At summary judgment, a court must view all facts in the light most favorable to the nonmoving party and draw all justifiable inferences in its favor. Auto. Techs. Int'l v. BMW of N. Am., Inc., 501 F.3d 1274, 1281 (Fed. Cir. 2007).

Once the moving party identifies those portions of the "the pleadings, the discovery and disclosure materials on file, and any

---

document does not comply with Local Rule of Civil Procedure 7.02(a) and (b) ("Rule 7.02"), which limits memoranda in response to "twenty-five [double-spaced] pages." See Fed. R. Civ. P. 83 (authorizing district courts to make and amend rules, not inconsistent with the Federal Rules of Civil Procedure, governing practices within the district court). Although Rule 7.02 empowers the Court to enlarge the page limits for good cause shown, Teva made no such motion. Instead, it essentially filed a seventy-five page brief without the leave of the Court.

affidavits [that] show that there is no genuine issue as to any material fact," Fed. R. Civ. P. 56(c), the burden then shifts to the non-moving party to set forth "'some evidence in the record sufficient to suggest that his view of the issue might be adopted by a reasonable factfinder.'" Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 45 F.3d 1550, 1561 (Fed. Cir. 1995) (quoting Resolution Trust Corp. v. Juergens, 965 F.2d 149, 151 (7th Cir. 1992)). The non-moving party, however, cannot rely on contradictions or conflicts within its own evidence. Barwick v. Celotex Corp., 736 F.2d 946, 960 (4th Cir. 1984).

III. LEGAL ANALYSIS

A.

An infringement analysis entails two steps. The first step determines the meaning and scope of the patent claims asserted to be infringed. The second step compares the properly construed claims to the device accused of infringing. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996) (citations omitted). Here, the Court has already determined the meaning and scope of the disputed claims, and thus must compare Teva's proposed generic drug product to those claims. Importantly, it must compare Teva's proposed generic drug product to the asserted claims of the patents-in-suit rather than

to Dey's product, Perforomist®. See Zenith Labs., Inc. v. Bristol-Meyers Squibb Co., 19 F.3d 1418, 1423 (Fed. Cir. 1994).

When comparing the accused device to the claims, "the accused device infringes if it incorporates every limitation of a claim, either literally or under the doctrine of equivalents." MicroStrategy Inc. v. Business Objects, S.A., 429 F.3d 1344, 1352 (Fed. Cir. 2005) (citations omitted).[2] Thus, if "even one claim limitation is missing or not met, there is no literal infringement." Id. Moreover, where a dependant claim is allegedly infringed, the Court cannot find literal infringement unless all of the elements and limitations in both the dependent claim and the independent claim on which it relies have been infringed. See Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989).

"[W]hile claim construction is a question of law, infringement . . . is a question of fact." Serio-US Ind., Inc. v. Plastic Recovery Tech. Corp., 459 F.3d 1311, 1316 (Fed. Cir. 2006) (citing Optical Disc. Corp. v. Del Mar Avionics, 208 F.3d 1324, 1333-34 (Fed. Cir. 2000); Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998); Cybor Corp. v. FAS Techs. Inc., 138 F.3d 1448,

[2] Dey alleges only literal infringement in this motion; thus, it has waived any argument of infringement under the doctrine of equivalents. See Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1355 (Fed. Cir. 2003).

1451 (Fed. Cir. 1998) (en banc)). Where "the parties do not dispute any relevant facts regarding the accused product . . ., the question of literal infringement collapses into claim construction and is amenable to summary judgment." Gen. Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 983 (Fed. Cir. 1997). "[I]in an action [such as this, brought] under § 271(e)(2)(A) . . . the alleged infringement is not based upon a product that actually exists and can be compared to the claim limitations." Apotex, Inc. v. Cephalon, Inc., 2:06-CV-2768, 2012 WL 1080148, *6 (E.D. Pa. Mar. 28, 2012), aff'd, 500 F. App'x 959 (Fed. Cir. 2013).

Nevertheless, "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." Id. (quoting Abbott Laboratories v. TorPharm, Inc., 300 F.3d 1367, 1373 (Fed. Cir. 2002)). Thus, the Court must limit its inquiry "to the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder." Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1248-49 (Fed. Cir. 2000).

Dey, as the patentee, bears the burden of proving infringement by a preponderance of the evidence. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991). "'The burden of showing something by a preponderance of the evidence . . . simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.'" Salem v. Holder, 647 F.3d 111, 116 (4th Cir. 2011) (citing United States v. Manigan, 592 F.3d 621, 631 (4th Cir. 2010)). At bottom, "[s]ummary judgment on the issue of infringement [or noninfringement] is proper when no reasonable jury could find that every limitation recited in a properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalentS." PC Connector Solutions, LLC v. SmartDisk Corp., 406 F.3d 1359, 1364 (Fed. Cir. 2005) (citing Bai, 160 F.3d at 1353-54).

B.

Dey argues there is no genuine dispute of material fact that Teva's proposed generic drug product infringes claims 1 and 65 of the '344 Patent, and that it is entitled to judgment as a matter of law as to these claims. Dey bears the burden of proving infringement by a preponderance at trial. The Court therefore will first review claims 1 and 65, and then consider Dey's evidence that

each and every limitation recited in those claims is found in Teva's proposed generic drug product.

Claim 1 of the '344 Patent recites:

> A pharmaceutical composition, comprising formoterol, or a derivative thereof, in a pharmacologically suitable aqueous solution, wherein the composition is stable during long term storage, the composition is formulated at a concentration effect[ive] for bronchodilation by nebulization, and the composition is suitable for direct administration to a subject in need thereof, without propellant and without dilution of the composition prior to administration.

Claim 65 of the '344 Patent recites:

> An article of manufacture, comprising packaging material, an aqueous composition comprising the composition of claim 1 formulated for single dosage administration, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.

Claim 65 depends from independent claim 1, and thus includes all of the limitations of claim 1. (Dkt. No. 160).

C.

The Court will first compare the limitations recited in claim 1 of the '344 Patent with the evidence adduced by Dey in support of its motion for summary judgment on the issue of infringement.

1. Pharmaceutical Composition

Limitation	Portion of the record cited by Dey in support of partial summary judgment
A pharmaceutical composition	**Table 2.3.P.1-1 (dkt. no 160-9 at 1)** **• Active ingredient, formoterol fumarte dihydrate** **• Various inactive ingredients** **Teva's proposed product label (dkt. no. 160-11 at 23)** **• "Each vial contains 2 mL of a clear colorless solution composed of formoterol fumarate dihydrate"**

The first phrase of claim 1 recites: "A pharmaceutical composition . . . ." In its Markman order, the Court construed that phrase to mean "a medicinal formulation containing an active drug and inert excipients." (Dkt. No. 99 at 41). Based upon Table 2.3.P.1-1: Unit Composition for Formoterol Fumurate Inhalation Solution ("Table 2.3.P.1-1") (dkt. no. 160-9 at 1), excerpted from Teva's ANDA, and Teva's proposed label for its proposed generic drug product (dkt. no. 160-11 at 23), Dey argues that Teva's proposed generic drug product contains a "pharmaceutical composition comprising formoterol," and, thus, the limitation is found in Teva's proposed generic drug product.

Table 2.3.P.1-1, in relevant part, states that the active component in Teva's proposed generic drug product is "Formoterol Fumarate Dihydrate, USP," and that the formoterol solution also contains Citric Acid, USP (buffering agent), Sodium Citrate, USP (buffering agent), Sodium Chloride, USP (tonicity agent), and Water for Injection, USP (vehicle). (Dkt. No. 160-9 at 1). Teva's proposed label for the proposed generic drug product also states that

> [f]ormoterol fumarate inhalation solution is supplied as 2 mL of formoterol fumarate inhalation solution packaged in a 3 mL single-use low-density polyethelene vial and overwrapped in a foil pouch. Each vial contains 2 mL of a clear, colorless solution composed of formoterol fumarate dihydrate equivalent to 20 mcg of formoterol fumarate in an isotonic, sterile aqueous solution containing sodium chloride, pH adjusted to 5.0 with citric acid and sodium citrate.

(Dkt. No. 160-11 at 23).

Importantly, "Teva does not contest that [its] formoterol fumarate solution is a medicinal formulation containing formoterol fumarate dihydrate as the active pharmaceutical ingredient and inert excipients such as water and sodium chloride." (Dkt. No. 163-1 at 19). Nor does "Teva[] contest [that] the table is from Teva's ANDA and sets forth the general composition of Teva's generic formoterol fumarate inhalation solution and the corresponding pharmaceutical function and amount per unit basis of each component." Id.

Consequently, the evidence preponderates in favor of the conclusion that Teva's proposed generic drug product contains a medicinal formulation composed of an active drug (Formoterol Fumarate Dihydrate, USP) and several excipients, or inactive substances, including citric acid, sodium citrate, sodium chloride, and water. Thus, when compared to the Court's construction of the limitation, "pharmaceutical composition," the first limitation of claim 1 plainly is found in Teva's proposed generic drug product.

2. Comprising Formoterol, or a Derivative Thereof

Limitation	Portion of the record cited by Dey in support of partial summary judgment
Comprising formoterol, or a derivative thereof	**Table 2.3.P.1-1 (dkt. no. 160-9 at 1)** **• Active ingredient, formoterol fumarte dihydrate** **Teva's proposed product label (dkt. no. 160-11 at 23)** **• "Each vial contains 2 mL of a clear colorless solution composed of formoterol fumarate dihydrate"**

Claim 1 next recites that the pharmaceutical composition is comprised of "formoterol, or a derivative therof." Once again, Dey relies on Table 2.3.P.1-1 (dkt. no. 160-9 at 1), and Teva's proposed product label (dkt. no. 160-11 at 23), as evidence that Teva's proposed generic drug product is a pharmaceutical composition "comprising formoterol, or a derivative thereof."

Dey's evidence supports the conclusion that Teva's proposed generic drug product contains this limitation. Specifically, Table 2.3.P.1-1 states that "Formoterol Fumuarte Dihydrate, USP" is the active ingredient of Teva's proposed generic drug product (dkt. no. 160-9 at 1), and Teva's proposed label for the proposed generic drug product names "formoterol fumarate dihydrate" as the proposed generic drug product's active ingredient. (Dkt. No. 160-11 at 23). Recall that "Teva does not contest that [its] formoterol fumarate solution is a medicinal formulation containing formoteral fumarate dihydrate as the active pharmaceutical ingredient and inert excipients such as water and sodium chloride," (dkt. no. 163-1 at 19), or that Table 2.3.P.1-1 "sets forth the general composition of Teva's generic formoterol fumarate inhalation solution and the corresponding pharmaceutical function and amount per unit basis of each component." Id. In short, Dey has met its initial burden on summary judgment of establishing the presence of this limitation in Teva's proposed generic drug product.

3. In a Pharmacologically Suitable Aqueous Solution

Limitation	Portion of the record cited by Dey in support of partial summary judgment

In a pharmacologically suitable aqueous solution	**Table 2.3.P.1-1 (dkt. no. 160-9 at 1)** **• Vehicle, water for injection** **Teva's proposed product label (dkt. no. 160-11 at 23)** **• "isotonic, sterile aqueous solution"**

Next, Dey argues that the pharmaceutical composition found in Teva's proposed generic drug product is "formulated as a pharmacologically suitable aqueous[3] solution," thus satisfying the third limitation found in claim 1. Again, Dey draws upon Table 2.3.P.1-1 (dkt. no. 160-9 at 1) and Teva's proposed product label for the proposed generic drug product. (Dkt. No. 160-11 at 23).

Table 2.3.P.1-1 states that Teva's proposed generic drug product contains "water for injection." (Dkt. No. 160-9 at 1), and Teva's proposed product label states that "[e]ach vial contains 2 mL of clear, colorless solution composed of formoterol fumarate dihydrate . . . in an isotonic, sterile aqueous solution." (Dkt. No. 160-11 at 23). Moreover, Teva does not contest that its "formoterol fumarate solution is a medicinal formulation containing formoteral fumarate dihydrate as the active pharmaceutical ingredient and inert excipients such as water and sodium chloride." (Dkt. No. 163-1 at 19). It follows from this evidence that it is

[3] Merriam-Webster's Third International Dictionary, Unabridged 2092 (Merriam-Webster, Inc., 3d ed. 2002)("Webster's") second definition of "aqueous" – the one relevant here – is "made from, with, or by means of water." Webster's 108 (2002).

more likely than not that Teva's proposed generic product is formulated as a pharmacologically suitable aqueous solution. Dey thus has met its initial burden on summary judgment as to this limitation.

4. Wherein the Composition is Stable During Long Term Storage

Limitation	Portion of the record cited by Dey in support of partial summary judgment
Wherein the composition is stable during long term storage	**Teva's long-term stability studies (dkt. no. 160-12 at 1)** **Teva's Development Stability Report (dkt. no. 160-14 at 12)** • **"All the specification limits were met for product"**

The Court's Markman order already construed the phrase "stable during long term storage" to mean that "the composition has an estimated shelf-life of greater than 1, 2 or 3 months usage time at 25° C and greater than or equal to 1, 2 or 3 years storage time at 5° C." It also construed the phrase "shelf life" to mean "the period of time during which a drug may be stored and remains suitable for use." (Dkt. No. 99 at 41).

Dey points to two items in the record to support its contention that this limitation is found in Teva's proposed generic

drug product. First, it offers Teva's own long-term stability study, which states in pertinent part:

> In support of a 24 month expiration date, the stability data generated from up to 12 weeks storage under accelerated conditions (25° +/- 2°C/40 +/-5% RH) and T104 weeks storage under recommended conditions (5 +/- 3°C) for the product packaged either in strips of five (5) primary containers per pouch or as a single primary containers per pouch specifications respectively, are presented in the following tables. All data have met the proposed specifications for the stability time points tested to date.

(Dkt. No. 160-12 at 1). Second, Dey highlights the conclusion of Teva's Development Stability Report that "[a]ll the specification limits were met for product stored at accelerated conditions of 25° C (+/-2° C) / 40%RH (+/-5%RH) for 12 weeks, and for product stored at long term storage conditions of 5° C (+/- 3° C) for 104 weeks." (Dkt. No. 160-14 at 12)

In other words, Teva's own testing establishes that its proposed generic drug product is stable at 25° C for twelve weeks, or three months, and for 104 weeks, or two years, at 5° C. Those results indicate that it is indeed more likely than not that Teva's proposed generic drug product contains the limitation, "stable during long term storage." Thus, Dey has met its initial burden on summary judgment as to this limitation.

5. Formulated at a Concentration Effective for Bronchodilation

Limitation	Portion of the record cited by Dey in support of partial summary judgment
The composition is formulated at a concentration effect[ive] for bronchodilation	**Teva's proposed label (dkt. no. 160-11 at 24, 36, 14)**

Claim 1 next recites that the "composition [i.e., the pharmaceutical composition] is formulated at a concentration effective for bronchodilation." To demonstrate that Teva's proposed generic drug product contains this limitation, Dey again points to portions of Teva's proposed label, which states:

- "Inhaled formoterol fumarate acts locally in the lungs as a bronchodilator" (dkt. no. 160-11 at 24);
- "Formoterol fumarate inhalation solution is a medicine called a long-acting beta$_2$-agonist (LABA) or long-acting broncho-dilator" id. at 36);
- Formoterol fumarate inhalation solution is indicated for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction . . . ." Id. at 14.

These statements indicate that Teva intends its proposed generic product to act as a bronchodilator. Indeed, Teva is statutorily bound to do so. See Apotex, Inc., 2012 WL 1080148, at *6. Moreover, "Teva does not dispute that its formoterol fumarate

inhalation solution is formulated at a concentration of formoterol fumarate such that when administered to a patient via nebulization, the nebulized solution is effective for bronchodilation in certain COPD patients." (Dkt. No. 163-1 at 21). Accordingly, Dey has met its initial burden on summary judgment of adducing evidence that preponderates in favor of the conclusion that Teva's proposed generic product is formulated at a concentration effective for bronchodilation.

6. Nebulization

Limitation	Portion of the record cited by Dey in support of partial summary judgment
By nebulization	**Teva's proposed label (dkt. no. 160-11 at 10, 14, 35, 40)**

The pharmaceutical composition described in claim 1 also must be "formulated at a concentration effect[ive] for bronchodilation by nebulization." Once again, Dey relies on portions of Teva's proposed label to support its contention that this claim is found in Teva's proposed generic drug product. Dey points to Teva's proposed label, which states as follows:

- "For use with a standard jet nebulizer (with a facemask or mouthpiece) connected to an air compressor (2)" (dkt. no. 160-11 at 10);

- "The recommended dose of formoterol fumarate inhalation solution is one 20 meg unit-dose administered twice daily (morning and evening) by nebulization" id. at 14;
- "It is important that patients understand how to use formoterol fumuarate inhalation solution with a nebulizer" id. at 35; and
- "Formoterol fumarate inhalation solution is used only in a standard jet nebulizer machine connected to an air compressor." Id. at 40.

Moreover, "Teva does not dispute that its formoterol fumarate solution is formulated at a concentration of formoterol fumurate such that when administered to a patient via nebulization, the nebulized solution is effective for bronchodilation in certain COPD patients." (Dkt. No. 163-1 at 21). Considering the statements on Teva's proposed label and Teva's telling admission, the Court concludes that Teva's proposed generic product includes the limitation "by nebulization." Dey therefore has met its initial burden on summary judgment as to this particular limitation.

7. Suitable for Direct Administration To a Subject in Need Thereof, Without Propellant and Without Dilution of the Composition Prior to Administration

Limitation	Portion of the record cited by Dey in support of partial summary judgment

Suitable for direct administration to a subject in need thereof, without propellant and without dilution of the composition prior to administration	**Teva's proposed label (dkt. no. 160-11 at 38, 41-42, 63)** **Table 2.3.P.1-1 (dkt. no 160-9 at 1)**

Dey argues that Teva's proposed generic product satisfies this limitation of claim 1. Importantly, the Court has construed the phrase "formulated at a concentration suitable for direct administration," which is a component of this limitation, to mean "ready to administer directly to a subject in need thereof, without mixing or diluting." (Dkt. No. 99 at 7, 41).

Teva's proposed label states that the "formoterol fumarate inhalation solution [is to be used] exactly as prescribed. One ready-to-use vial of formoterol fumarate inhalation solution is one dose." (Dkt. No. 160-11 at 38); see also (Dkt. No. 160-11 at 63 (same)). It also states that Teva's proposed generic drug product "does not require dilution prior to administration by nebulization." Id. at 24. The detailed instructions included in the proposed generic drug product label do not direct users to mix the pharmaceutical composition with any other substance before administering it. See id. at 41-42. Nor does Teva's proposed generic drug product contain any ingredient described as a "propellant." See (Dkt. No. 160-9 at 1) (listing ingredients of

Teva's proposed generic drug product, which include active components, buffering agents, tonicity agents, and a vehicle). These omissions, and Teva's characterization of its proposed generic drug product as "ready to use," support the conclusion that Teva's proposed generic product satisfies the limitation of claim 1, "suitable for direct administration without propellant and without dilution of the composition prior to administration."

The Court turns next to the limitations contained in claim 65 of the '344 Patent.

8. Article of Manufacture

Limitation	Portion of the record cited by Dey in support of partial summary judgment
Article of manufacture is something that contains: • **packaging material;** • **a composition, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction; and** • **a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.**	**Teva's proposed label (dkt. no. 160-11 at 1, 5, 7, and 14)**

The Court has construed "article of manufacture" (dkt. no. 99) to mean something that "contains (1) packaging material, (2) a composition, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and (3) a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction." Dey argues that Teva's proposed generic drug product meets these three elements of an "article of manfacture" because (1) Teva's proposed generic product is sold in packaging material; (2) the product is indicated for the treatment of chronic obstructive pulmonary disease ("COPD"); and (3) the product includes a label that instructs users how to administer the drug.

Dey's contention that Teva's proposed label indicates its proposed generic drug product contains packaging material is correct. For the purposes of the patents-in-suit, "packing material" means "blister packs, bottles, tubes, inhalers, pumps, bags, vials, containers, syringes, bottles, and any packaging material suitable for a selected formulation and intended mode of administration and treatment." (Dkt. No. 99 at 42-43). Teva's proposed label indicates that its proposed generic drug product

contains a carton (dkt. no. 160-11 at 1), a five-pack nebule, id. at 5, and a foil pack, id. at 7, all of which plainly satisfy this Court's construction of the term "packaging material."

Moreover, Teva's proposed label states that "[f]ormoterol fumarate inhalation solution is indicated for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction . . . ." Id. at 14. That statement establishes both that Teva's proposed generic drug product is useful for the treatment of bronchoconstriction, and also that the label indicates such utility. Dey therefore has met its initial burden on summary judgment as to the limitation "article of manufacture."[4]

2. Formulated for Single Dosage Administration

Dey argues that Teva's proposed generic drug product is "formulated for single dosage administration," and thus contains the final limitation of claim 65. The Court's Markman order construed that phrase to mean "formulated in a quantity that is taken or administered at one time." (Dkt. No. 99 at 42).

[4] Teva objects that its proposed generic drug product is not an article of manufacture because it does not include a label that states, "the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction . . . ." (Dkt. No. 163-1 at 23). The Court will address this argument, which is also raised in Teva's response brief (dkt. no. 163 at 20 - 22), infra.

Additionally, the Court noted that the ordinary meaning of the term "formulate" is "create." (Dkt. No. 99 at 16).

Teva's proposed label for its generic drug product states that the "formoterol fumarate inhalation solution [is to be used] exactly as prescribed. One ready-to-use vial of formoterol fumarate inhalation solution is one dose." (Dkt. No. 160-11 at 38); see also (Dkt. No. 160-11 at 63 (same)). Given the ordinary meaning of "formulated" noted in the Court's Markman order, Teva's proposed label plainly indicates that the formoterol solution, which is a part of its proposed generic drug product, is to be "created" (dkt. no. 99 at 16) for use in a "ready-to-use vial" which, in turn, is one dose of the proposed generic drug product. (Dkt. No. 160-11 at 38); see also (Dkt. No. 160-11 at 63 (same)). When compared to the language of claim 65 – that the described "article of manufacture" is comprised, in part, by "an aqueous composition comprising the composition of claim 1 formulated for single dosage administration" – Teva's statement supports Dey's contention that this limitation is, more likely than not, present in Teva's proposed generic drug product. Dey, therefore, has met its initial burden on summary judgment as to this limitation.

Teva's response, that "[a] drug product is not 'formulated' for single dose administration," is inapposite. "Drug product" is Dey's phrase. See (Dkt. No. 160 at 9). It is not found in claim 65

of the '344 Patent. Rather, claim 65 requires the "aqueous composition comprising the composition of claim 1" to be formulated for "single dose administration." MicroStrategy Inc., 429 F.3d at 1352 ("the accused device infringes if it incorporates every limitation of a claim, either literally or under the doctrine of equivalents").

In sum, the Court concludes that Dey has identified portions of Teva's proposed label and other discovery materials that "show that there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). With regard to claim 1, Dey has identified portions of the record that support its contention that each limitation of claim 1 is contained in Teva's proposed generic drug product. Likewise, Dey has also identified portions of the record that support its contention that Teva's proposed generic drug product contains every limitation of claim 65.

Based on these conclusions, the burden now shifts to Teva, the non-moving party, to set forth "'some evidence in the record sufficient to suggest that [its] view of the issue might be adopted by a reasonable factfinder.'" Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 45 F.3d 1550, 1561 (Fed. Cir. 1995) (quoting Resolution Trust Corp. v. Juergens, 965 F.2d 149, 151 (7th Cir. 1992)). Absent such a showing by Teva, Dey is entitled to partial summary judgment on its contention that, as a

matter of law, Teva has infringed claims 1 and 65 of the '344 Patent.

D.

Teva's response to Dey's motion for partial summary judgment focuses on what it characterizes as material factual disputes as to two limitations – the first in claim 1, and the second in claim 65. First, Teva argues that its proposed generic drug product does not contain the limitation of long-term stability found in claim 1 because, absent a light-protective foil overwrap, the formoterol solution degrades when exposed to light. Teva argues that the formoterol solution therefore is not "stable during long term storage." (Dkt. No. 163 at 4).

Teva also argues that its proposed generic drug product does not contain the label required by claim 65 because the label in its proposed generic product is not found on the vial containing the formoterol solution. Id. at 15. Alternatively, it contends that its label does not satisfy claim 65 because it does not include any matter stating that the formoterol solution "is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled

bronchoconstriction," as required by claim 65. Id. at 163. The Court will consider each of these arguments in turn.[5]

1.

Claim 1 of the '344 Patent recites:

> A pharmaceutical composition, comprising formoterol, or a derivative thereof, in a pharmacologically suitable aqueous solution, wherein the composition is stable during long term storage, the composition is formulated at a concentration effect[ive] for bronchodilation by nebulization, and the composition is suitable for direct administration to a subject in need thereof, without propellant and without dilution of the composition prior to administration.

Teva reasons that claim 1 requires a pharmaceutical composition, comprised of formoterol (or formoterol derivative) in a pharmacologically aqueous solution, in which the composition is

[5] Throughout its "Response to Plaintiffs' Apparent Statement of Facts and Teva's Rebuttal Statement of Additional Material Facts in Opposition to Dey's Motion for Partial Summary Judgment" (dkt. no. 163-1), Teva contests various statements made in Dey's opening brief "to the extent that Dey implies that 'Teva's generic product' is defined as Teva's formoterol fumarate inhalation solution itself outside of its primary and secondary packaging." See, e.g., id. at 19. The Court presumes that, were Teva actually relying on this argument to withstand partial summary judgment, it would have placed it squarely within its response brief. Nevertheless, after a review of Teva's objections, the Court finds the statement conclusory, and therefore "insufficient to shoulder the non-movant's burden." TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1372 (Fed. Cir. 2002) (citing Johnston v. IVAC Corp., 885 F.2d 1574, 1578 (Fed. Cir. 1989)).

stable during long term storage. Based on its conception of claim 1, Teva concludes that, because "composition" refers to the preceding phrase, "pharmaceutical composition," claim 1 plainly requires the pharmaceutical composition **itself** to be stable during long term storage. Therefore, according to Teva, because the formoterol solution - absent any protective overwrap - included in its proposed generic drug product degrades when exposed to sunlight, the formoterol solution, i.e., pharmaceutical composition, is not "stable during long term storage," does not satisfy claim 1, and therefore does not infringe the '344 Patent.

Teva's argument fails for the fundamental reason that claim 1 of the '344 Patent simply does not address photostability. See (Dkt. No. 165-3 at 3-4). One cannot find it in the body of the '344 Patent. (Dkt. No. 163-18 at 8). It is not referenced in the construction of the limitation "stable during long term storage." (Dkt. No. 99 at 42) ("'Stable during long term storage' means 'the composition has an estimated shelf-life of greater than 1, 2 or 3 months usage time at 25° C and greater than or equal to 1, 2 or 3 years storage time at 5° C.'"). Nor is any reference to photostability found in the undisputed definition of "stable" contained in the '344 and '953 patents.

> As used herein, the stability of a composition provided herein refers to the length of time at a given temperature that is greater than 80%, 85%, 90% or 95% of

> the initial amount of active ingredient, e.g., formoterol, is present in the composition. Thus, for example, a composition that is stable for 30 days at 25◦ C. would have greater than 80%, 85%, 90% or 95% of the initial amount of active ingredient present in the composition at 30 days following storage at 25◦ C.

'344, col. 5, ll. 30-38; '953, col. 5, ll. 40-48.

That definition includes two independent variables, time and temperature, and one dependent variable, the percentage of the initial amount of active ingredient present in the composition following a period of storage. See id. Contrary to Teva's rebuttal argument, the independent variable of exposure to light and/or ultraviolet ("UV") radiation simply is not part of that definition. In other words, the degradation of the amount of active ingredient present in the composition due to light exposure – within or without a light-protective foil overwrap – is not a variable that is relevant to the determination of long term stability under the undisputed definition of "stability" found in the '344 Patent, or the Court's construction of the limitation "stable during long storage." See (Dkt. No. 163 at 9).[6]

[6] This conclusion carries two implications. First, photostability also is not a limitation implicit in claim 65 of the '344 Patent, because that claim depends upon claim 1. Second, because the Court has concluded that photostability is irrelevant to the issue of long term stability, it need not address Teva's argument that its formoterol solution itself, absent packaging, must remain stable during long term storage.

It appears that Teva has relocated its "intrinsic stability" argument from the context of the limitation, "pharmaceutical composition," where Teva placed it during the Markman briefing, to the subsequent limitation, "stable during long term storage." That conclusion is obvious when one considers that the bottom line of Teva's argument on summary judgment is that, in order to be considered stable during long term storage, the percentage of the initial amount of active ingredient present in the pharmaceutical composition described in claim 1, absent any sort of packaging, cannot decrease when exposed to light. Stated differently, Teva argues that the pharmaceutical composition described in claim 1 possesses the essential quality of photostability, i.e., the pharmaceutical composition is intrinsically stable.

At bottom, "Dey never asserted that its pharmaceutical compositions had an inherent characteristic of 'stability' distinct from being 'stable during long term storage,'" (dkt. no. 99 at 27), a limitation defined by the variables of the time and temperature. Thus, for the same reason that it rejected Teva's argument in its Markman opinion, the Court rejects the argument again on summary judgment. See id. at 19-27. Therefore, Teva's objection that its proposed generic drug product is not stable during long term storage, absent a foil overwrap, because the formoterol solution

included in that product degrades when exposed to light, fails as a matter of law.

2.

Next, Teva argues that its proposed generic drug does not contain a "label," as required by claim 65 of the '344 Patent, because the label contained in its proposed generic product is not found "upon" the vial containing the formoterol solution. Id. at 15. In support of its argument, Teva relies on the construction of that limitation adopted by the Southern District of New York in Dey, Inc. v. Sepracor, Inc., No. 07 CIV. 2353 JGK, 2012 WL 1720614 (S.D.N.Y. May 16, 2012) (the "New York litigation"), a parallel proceeding in which claim 65 of the '344 Patent also was in dispute.

Dey first argues that the construction of "label" adopted in the New York litigation has no preclusive effect here as that construction was issued subsequent to the construction by this Court. Second, Dey contends that, because the New York litigation ended not on summary judgment or following a trial, but with a settlement between the parties, the claim construction in that case is not binding in this proceeding. Finally, Dey asserts that it will suffer undue prejudice should the Court adopt the construction from the New York litigation at this late date because, in the year

following the claim construction ruling in that case, Teva never sought to raise the issue here.

In order to adequately address Teva's response, the Court will first review the proceedings in this case and those in the New York litigation. It will then address the doctrine of res judicata, and more specifically, issue preclusion.

(a)

In March, 2007, Dey filed suit against Sunovian Pharmaceuticals, Inc. ("Sunovian")[7] in the Southern District of New York, alleging that Sunovian's product, Brovana®, infringed the '344, '953, '362, and '645 patents.[8] Dey, Inc. v. Sepracor, Inc., 847 F. Supp. 2d 541, 547 (S.D.N.Y. 2012) rev'd and remanded sub nom. Dey, L.P. v. Sunovion Pharmaceuticals, Inc., 715 F.3d 1351 (Fed. Cir. 2013). Thereafter, on June 23, 2009, Dey filed a complaint in this Court alleging that Teva's proposed generic drug product infringed those same patents. See (Dkt. No. 1).

On June 17, 2011, this Court's Markman order construed certain claims at issue in the patents-in-suit, including "label," a limitation found in claim 65 of the '344 Patent. Significantly,

[7] At the time of filing, Sunovian Pharmaceuticals, Inc. ("Sunovian") was known as Sepracor, Inc. ("Sepracor").

[8] Dey also alleged that Sunovian's product infringed United States Patent Numbers 7,465,756; 7,473,710; and 7,541,385. Dey, Inc., 847 F. Supp. 2d at 547.

"label" was not among the terms disputed by the parties. Accordingly, the Court adopted the parties' proposed construction that "'label' means "Printed matter included with the article of manufacture that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.'" (Dkt. No. 99 at 43).

Nearly a year later, on May 16, 2012, the district court in the New York litigation construed the term "label," found in claim 65 of the '344 Patent. Dey, Inc., 2012 WL 1720614, at *10-11. Unlike the instant proceeding, however, Dey and Sunovian contested the construction of "label." Id. The Markman order in the New York litigation adopted Sunovian's proposed construction, and construed "label" to mean "[a] display of written, printed, or graphic matter upon the immediate container surrounding the pharmaceutical product that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction." Id. Eight days after entry of that Markman order, on May 24, 2012, the district court entered a Final Judgment and Order in the New York litigation. (Dkt. No. 163-18 at 120-124).

(b)

Because the application of issue preclusion is not a matter within the exclusive jurisdiction of the Federal Circuit, the Court will apply the relevant law of the Fourth Circuit. See Vardon Golf Co. v. Karsten Mfg. Corp., 294 F.3d 1330, 1333 (Fed. Cir. 2002). Issue preclusion, a subset of res judicata, "forecloses the relitigation of issues of fact or law that are identical to issues which have been actually determined and necessarily decided in prior litigation in which the party against whom [collateral estoppel] is asserted had a full and fair opportunity to litigate." In re Microsoft Corp. Antitrust Litig., 355 F.3d 322, 326 (4th Cir. 2004) (quoting Sedlack v. Braswell Servs. Group, Inc., 134 F.3d 219, 224 (4th Cir. 1998) (internal quotation marks and citation omitted)).[9]

[9] The Federal Circuit recently issued an opinion in which it set out that circuit's law as to issue preclusion. See Levi Strauss & Co. v. Abercrombie & Fitch Trading Co., No. 2012-1495, 2013 WL 2991065, at *3-4, ---- F.3d ---- (Fed. Cir. June 18, 2013). That case, however, was an appeal from The United States Patent and Trademark Office, Trademark Trial and Appeal Board, not an appeal from a district court. In other words, Vardon still requires the Court to apply the issue preclusion rule of the Fourth Circuit. See Senyszyn v. Dep't of Treasury, 465 F. App'x 935, 941 (Fed. Cir. 2012).

Regardless, the tests of the Fourth and Federal Circuit are relatively similar. Compare In re Microsoft Corp. Antitrust Litig., 355 F.3d at 326, with Levi Strauss & Co., 2013 WL 2991065, at *3-4 ("We have stated four preconditions for a second suit to be barred by issue preclusion: (1) identity of the issues in a prior proceeding; (2) the issues were actually litigated; (3) the determination of the issues was necessary to the resulting judgment; and (4) the party defending against preclusion had a full and fair opportunity to litigate the issues.").

To preclude an issue from relitigation, the proponent of preclusion must demonstrate that

> (1) the issue or fact is identical to the one previously litigated;
>
> (2) the issue or fact was actually resolved in the prior proceeding;
>
> (3) the issue or fact was critical and necessary to the judgment in the prior proceeding;
> (4) the judgment in the prior proceeding is final and valid; and
>
> (5) the party to be foreclosed by the prior resolution of the issue or fact had a full and fair opportunity to litigate the issue or fact in the prior proceeding.

Id. "The burden is on the party asserting collateral estoppel to establish its predicates, and this of course includes presenting an adequate record for the purpose." Allen v. Zurich Ins. Co., 667 F.2d 1162, 1166 (4th Cir. 1982).

Here, Teva, the proponent of issue preclusion, cannot meet its burden under Allen. Nearly one year before entry of the Markman order in the New York litigation, this Court adopted the construction of "label" jointly proposed by Dey and Teva. Even assuming, for argument's sake, that the Markman order in the New York litigation was a final order, it still was not "**previously** litigated," "resolved in the **prior proceeding**," "critical and necessary to the judgment in the **prior proceeding**," a "judgment in the **prior proceeding**," or "a **prior resolution** of the issue." In re

Microsoft Corp. Antitrust Litig., 355 F.3d at 326 (emphasis added). On that fact alone, it cannot preclude this Court from applying its own construction of "label".

Moreover, even if the district court in the New York litigation had construed "label" prior to this Court's construction of that same term, its Markman order is not a final order having preclusive effect. See, e.g. Powervip, Inc. v. Static Control Components, Inc., 1:08-CV-382, 2011 WL 2669059, at *6 (W.D. Mich. July 6, 2011) ("Given that in construing patent claims judges often must tread on alien ground, addressing scientific and technological concepts that even experts in the field my disagree on, and that district court judges' interpretations are overturned nearly half of the time, the Court questions the utility of applying issue preclusion to a Markman order."); DE Technologies, Inc. v. IShopUSA, Inc., 826 F. Supp. 2d 937, 941 (W.D. Va. 2011) ("the court declines to apply the doctrine of collateral estoppel to the court's prior Markman rulings"); Kollmorgen Corp. v. Yaskawa Electric Corp., 147 F.Supp.2d 464, 467 (W.D.Va. 2001). But see, e.g., TM Patents, L.P. v. International Business Machines Corp., 72 F.Supp.2d 370 (S.D.N.Y. 1999) (giving collateral estoppel effect to a Markman order).

Nor can Teva rely on the Final Order and Judgment entered in the New York litigation to imbue the Markman order in that case

with the preclusive effect it otherwise lacks. (Dkt. No. 163-18 at 120-124). The Final Order and Judgement is a consent decree, which has "elements of both judgment and contract, a dual character that results in different treatment for different purposes." Smyth ex rel. Smyth v. Rivero, 282 F.3d 268, 280 (4th Cir. 2002) (internal quotations omitted). "In most circumstances, it is recognized that consent agreements ordinarily are intended to preclude any further litigation on the claim presented but are not intended to preclude further litigation on any of the issues presented. Thus consent judgments ordinarily support claim preclusion but not issue preclusion." Arizona v. California, 530 U.S. 392, 414 (2000) (quoting 18 Charles Alan Wright, Arthur R. Miller, & Edward H. Cooper, Federal Practice and Procedure § 4443, pp. 384-385 (1981)).

The Federal Circuit addressed the preclusive effect of consent decrees upon subsequent litigation in Foster v. Hallco Mfg. Co., Inc., 947 F.2d 469, 480 (Fed. Cir. 1991):

> A rationale for the rule of issue preclusion is that once a legal or factual issue has been settled by the court after a trial in which it was fully and fairly litigated that **issue** should enjoy repose. Such litigated issues may not be relitigated even in an action on a different claim between the parties. Where a judgment between parties is entered by consent prior to trial on any issue, no issue may be said to have been fully, fairly or actually litigated. Thus, the general rule that issue preclusion does not arise from a consent judgment would allow Foster's challenge to validity on a different claim inasmuch as no issue was actually tried and disposed of by decision of the court in Foster I.

Foster, 947 F.2d at 480 (internal citations and quotations omitted) (emphasis in original). Nonetheless, "if a consent judgment, by its terms, indicates that the parties thereto intend to preclude any challenge to the validity of a particular patent, even in subsequent litigation involving a new cause of action, then that issue can be precluded. Id. at 480-81.

Here, the Final Order and Judgment in the New York litigation says nothing about the parties' intent to preclude any subsequent litigation as to claim 65 of the '344 Patent. (Dkt. No. 163-18 at 120-124). In fact, as Teva candidly acknowledges, it is silent as to claim 65. Absent an indication that the parties to that consent judgment intended to preclude any further interpretation of claim 65, this Court is left to apply the general rule that issue preclusion does not arise from a consent judgment, and accordingly, concludes that the Final Order and Judgment entered in the New York litigation does not preclude litigation as to claim 65 of the '344 Patent, using this Court's construction of that term.

3.

Finally, Teva argues that its proposed label does not contain the indication required by this Court's construction of that term. Specifically, Teva argues that its proposed label does not include the indication that its product is suited for the treatment of

asthma, which, according to Teva, the '344 Patent requires. See (Dkt. No. 163 at 20).

To address this argument, the Court turns first to claim 65 and the specifications contained in the '344 Patent.

Claim 65 states:

> An article of manufacture, comprising packaging material, an aqueous composition comprising the composition of claim 1 formulated for single dosage administration, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and **a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.**

(emphasis added). Helpfully, the '344 Patent does not leave "undesired and/or uncontrolled bronchoconstriction" undefined. See '344 Patent Col. 6, ll. 57-65. The specification defines the phrase as referring to "bronchoconstriction that results in or from a pathological symptom or condition. Pathological conditions include, but are not limited to, asthma and chronic obstructive pulmonary disease (COPD). Likewise, pathological symptoms include, but are not limited to, asthma and COPD." '344 Patent Col. 6, ll. 57-65.

After reviewing claim 65 and the relevant specification, the Court concludes that Teva's argument lacks merit. "Label,"as construed by this Court and without objection from Teva during the

claims construction process, merely requires that the printed matter included with the article of manufacture "indicate[] that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction." (Dkt. No. 99 at 43). The specification that defines "undesired and/or uncontrolled bronchoconstriction" provides that bronchoconstriction either results:

(1) in a pathological symptom, e.g., asthma or COPD; or

(2) from a pathological condition, e.g., asthma or COPD.

The specification further provides that relevant pathological symptoms and conditions are not limited to asthma or COPD. Similarly, printed matter which Teva proposes to include with its proposed generic product states that "[f]ormoterol fumarate inhalation solution is indicated . . . in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD)." (Dkt. No. 160-11 at 14); see also id. at 37.

Printed matter included with Teva's proposed ANDA product	**Specification of claim 65 of the '344 Patent defining "undesired and/or uncontrolled bronchoconstriction"**

"Formoterol fumarate inhalation solution is indicated for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with **chronic obstructive pulmonary disease (COPD)**, including bronchitis and emphysema." (Dkt. No. 160-11 at 14); see also id. at 37.	"[B]ronchoconstriction that results in or from a pathological symptom or condition. Pathological conditions include, but are not limited to, asthma and **chronic obstructive pulmonary disease** (COPD). Pathological symptoms include, but are not limited to, asthma and **COPD**."

In other words, Teva's label states that its proposed generic drug product is indicated for the maintenance treatment of bronchoconstriction in patients with COPD. That clearly satisfies the indication required by this Court's construction of the term "label." Teva's argument, that the '344 Patent requires an indication for the treatment of asthma, is not persuasive given the patent's specification that "undesired and/or uncontrolled bronchoconstriction" results "in or from a pathological symptom or condition," which include, but are not limited to, COPD and asthma. Teva therefore has failed to raise a genuine issue of material of fact that would preclude granting partial summary judgment of infringement to Dey.

IV. Conclusion

Dey has met its burden on summary judgment of showing that Teva's proposed generic drug product "[literally] incorporates every limitation of" claims 1 and 65 of the '344 Patent. MicroStrategy Inc., 429 F.3d at 1352, while Teva has failed to meet

its rebuttal burden to set forth "'some evidence in the record sufficient to suggest that [its] view of the issue might be adopted by a reasonable factfinder.'" Glaverbel Societe Anonyme, 45 F.3d at 1561. Accordingly, the Court **GRANTS** Dey's Motion for Partial Summary Judgment of Infringement. (Dkt. No. 159). This case remains on the Court's trial docket and is scheduled as the first case on Monday, July 29, 2013.

It is so **ORDERED**.

The Court directs the Clerk of Court to transmit copies of this Order to counsel of record.

DATED: July 17, 2013.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE